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Amendment
Attorney Docket No. S63.2B-10886-US01

Remarks

This Amendment is in response to the Office Action dated **January 24, 2007**.

Claim 9 has been amended. The last line of the claim recited "balloon".

Applicant has amended to the claim to delete the term "balloon" and to replace it with "expandable portion". There was no antecedent basis in the claim for "balloon". No new matter has been added.

Claims 1-22 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lim et al. (U.S. 6,946,173).

Applicants traverse the rejection.

Claims 1, 9 and 14 are independent claims.

Claim 1 of the present application is directed to an embodiment of a dilatation balloon including a first plasma polymerized layer which forms the outer most layer of the balloon.

Claim 9 is directed to an embodiment of an implantable medical device, which recites among other features, an expandable portion having a first plasma polymerized layer that forms the outer most layer of the expandable portion.

Claim 14 is directed to a method of providing a catheter balloon with an outer most plasma polymerized layer by exposing the balloon to a gaseous monomer composition, and exposing the gaseous monomer to electromagnetic waves.

In each embodiment, it is the outer most layer which is the plasma polymerized layer.

The plasma polymerized layer can provide a protective layer that can improve the durability, abrasion and tear resistance of a thin-walled balloon. See, for example, page 3, lines

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17-20.

It is asserted in the Office Action that:

Lim et al discloses in figures 1-3, a catheter (10) having a balloon (24) mounted on its distal end; wherein the balloon (24) comprises a first plasma polymerized layer which form the outer layer (33) of the balloon and a second plasma polymerized layer which considered to form on the inner layer (34) of the balloon; wherein the first and second plasma polymerized layers (33,34) are formed by the reaction of monomer selected from the group as claimed (col. 2-13) and a stent (30) mounted on the balloon. As to claim the method claims 14-21, the Wang et al device is capable of performing the method steps as recited in the claimed invention..

See page 2, section 2 of the Office Action.

This is incorrect.

Applicants submit that layer 33 is formed from a porous material, preferably having a node and fibril microstructure, such as ePTFE, and the second layer 34 is formed of a low tensile set polymer such as a silicone-polyurethane copolymer or a diene polymer, neither of which Lim et al. suggests is formed by plasma polymerization.

In the embodiment illustrated in FIG. 1, the balloon 24 comprises a first layer 33 formed of a porous material, preferably having a node and fibril microstructure, such as ePTFE, and a second layer 34 formed of a low tensile set polymer such as a silicone-polyurethane copolymer or a diene polymer. In a preferred embodiment, layer 34 is an inner layer relative to layer 33, although in other embodiments it may be an outer layer relative to layer 33.

Col. 7, lines 55-63.

Porous polymer materials, such as porous ePTFE, are formed by stretching the polymer material:

Typically, the ePTFE comprises a film of stretched material which is formed into the tubular member layer 33 by wrapping the ePTFE material around a mandrel to form a tube and then heating the wrapped material to fuse the wrapped material together.

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Col. 8, lines 5-9.

Therefore, neither layer 33 nor layer 34 disclosed by Lim et al. are plasma polymerized.

What Lim et al. do suggest, however, is to chemically modify the ePTFE or expanded polytetrafluorethylene layer to facilitate bonding layer 33 to layer 34.

In the embodiment illustrated in FIG. 1, the ePTFE layer 33 of the balloon 24 is chemically modified to provide a plasma polymerized film 35 which facilitates bonding layer 33 to layer 34.

Col. 8, lines 10-13.

Therefore, the plasma polymerized layer disclosed by Lim et al. cannot possibly form the outer most layer of any article.

Applicants submit that a rejection under 35 U.S.C. §102(b) requires that each and every element be disclosed by the reference. "Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983)." *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 221 USPQ 481, 485 (Fed. Cir. 1984).

Applicants submit that Lim et al. fail to disclose each and every element of Applicants' independent claims 1, 9 and 14, namely, an outermost plasma polymerized layer.

Claims 2-8 depend from claim 1, claims 10-13 depend from claim 9 and claims 15-22 depend from claim 14 and are not anticipated by Lim et al. for at least the reasons that claims 1, 9 and 14 are not anticipated by Lim et al.

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Applicants respectfully request withdrawal of the rejection of claims 1-22 under 35 U.S.C. §102(b) as being anticipated by Lim et al. (U.S. 6,946,173).

As to the assertion in the Office Action that Wang et al. device is capable of performing method steps as recited in the claimed invention, Applicants submit that the combination of Wang et al. and Lim et al., still fails to suggest having an outer most layer that is plasma polymerized.

Applicants submit that Wang et al. (U.S. 6,939,321) discloses:

...a balloon in which the balloon first layer has at least a section with a gas plasma-etched or chemical solution etched surface. The etched surface improves the strength of the bond between the first layer and the second layer and/or the catheter shaft.

Col. 2, lines 27-31. This was discussed at length in the Response mailed November 6, 2006.

Applicants submit that while there may be motivation to combine the invention of Wang et al. with Lim et al., the combination would simply result in another means of modifying the ePTFE layer 33 disclosed by Lim et al. in order to provide improved bonding between layer 33 and layer 34 (silicone-polyurethane copolymer or diene polymer) as disclosed at col. 8, lines 10-13 of Lim et al. Therefore the combination of Wang et al. with Lim et al. fails to suggest an outer most plasma polymerized layer for improved durability as recited in Applicants' independent claim 14.

Claims 15-22 depend from claim 14 and are not obvious over Lim et al. in view of Wang et al. for at least the reasons that claim 14 is not obvious over Lim et al. in view of Wang et al.

Therefore, Applicants respectfully request withdrawal of the rejection of claims 14-21 as obvious over Lim et al., U.S. 6,946,173, in view of Wang et al., U.S. 6,939,321.

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CONCLUSION

Claims 1-23 are pending in the Office Action. Applicants have added a new claim 23 which is seen as being patentably distinct from the art of record. Support for claim 23 may be found on pages 10-11 of the specification. No new matter has been added.

Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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